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Next Generation Education for Prevention: Defining Educational Needs, Attitudes, Concerns, Life Plans of 18 to 24 Year Old Daughters of *BRCA1/2* Mutations Carriers

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14. ABSTRACT

The goals of this study are to 1.) Describe in-depth the knowledge, attitudes, health behaviors, and life plans of a cohort of 40 daughters, ages 18-24 years, of mothers who are *BRCA1/2* mutation carriers, and 2.) Define specific health educational, psychological, insurance and medical needs of this population. We will then outline a health educational intervention targeted to identified needs of our target group. Our major data source will be the 40 in-depth, qualitative (semi-structured), telephone interviews we will conduct with 18-24 year old daughters of *BRCA1/2* mutation carriers. To date we have ascertained nearly 200 eligible mothers (many with multiple eligible daughters) at 3 Harvard teaching hospitals, gotten IRB approvals and an NIH Certificate of Confidentiality, developed and pre-tested our questionnaire and interview schedule and initiated piloting of these materials. We have also, however, encountered significant administrative hurdles which took longer than anticipated to clear, leaving us behind our original timeline. We anticipate catching up over the next year and, as originally anticipated, having quantitative findings and a qualitative report by the end of Year 2 when we expect to have conducted, transcribed, coded and analyzed 40 interviews with young adult daughters of *BRCA1/2* mutation carriers.

15. SUBJECT TERMS
Genetic testing, breast cancer, prevention, BRCA1/2, education

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Table of Contents

INTRODUCTION: Data from this study has the potential to answer an important question about genetic testing, i.e. what do those who are told by a relative, especially those informed as children, understand about hereditary breast cancer and what are the gaps or misperceptions in their knowledge? Are the gaps sufficient to cause us to challenge the present mode of spreading family information about hereditary risk by word of mouth through relatives? Are there ethical, more flexible models professionals we might adopt? We know that not all relatives are informed and that while much telling occurs soon after testing, in some cases, it is delayed many years. We know that parents who are mutation carriers worry most about impact on their children, yet we know little or nothing about what those children understand. We believe that an educational intervention to help inform young women as they come to an age at which they can make independent decisions about genetic testing would be valuable and potentially life-saving in its impact, encouraging them to seek genetic counseling and testing and to consider earlier and with more accurate information, the choices they face with regard to their hereditary cancer risk. The goals of this study are 1.) Describe in-depth the knowledge, attitudes, health behaviors, and life plans of a cohort of 40 daughters, ages 18-24 years, of mothers who are *BRCA1/2* mutation carriers, and 2.) Define specific health educational, psychological, insurance and medical needs of this population. Having this data will enable us to proceed towards development of a health educational intervention targeted to the identified needs of 18-24-year-old daughters of *BRCA1/2* mutation carriers, which will ultimately reduce mortality and morbidity. The major data source for this project will be the 40 in-depth, qualitative (semi-structured), telephone interviews we will conduct with 18-24 year old daughters of *BRCA1/2* mutation carriers. Additional quantitative data will be gathered from subjects including demographic and family history questions, the Brief Symptom Inventory-18, Impact of Event Scale and the Breast Cancer Genetic Testing Knowledge Scale. Subjects will be selected for maximal diversity (family history, socio-economic status, cultural differences), from among the age-eligible daughters of the approximately 1000 *BRCA1/2*-positive women who have tested at the DFCI, the Mass General Hospital(MGH), and the Beth Israel Deaconess Medical Center (BIDMC) between years 2000-2008.

BODY: This is a qualitative research project, a labor-intensive method which requires having all of the accumulated interviews completed, transcribed and analyzed and integrated with the quantitative data in order to draw conclusions. In line with our original timeline, it is anticipated that we will have research findings to report on or around month 24, to be included in the Year 2 Annual Report.

We have made important headway on getting this project underway and initiating the interviews, although we also encountered significant delaying IRB and other factors which have left us behind our original timeline for piloting the interviews. We have worked on all other possible aspects of the project, including consultation with consultants and ascertainment of close to 200 eligible mothers (many with multiple eligible daughters) at 3 Harvard teaching hospitals, development and pre-testing of questionnaire and interview schedule, development of a database for subject data, and beginning of consideration of possible coding topics for the interviews. We have consented our first pilot subject and will conduct her interview in the next 10 day upon receipt of her questionnaire. We have letters out to an additional 5 mothers seeking contact information for their daughters to do additional pilot interviews. We are very ready, once all IRB

issues are settled and the piloting is complete, to initiate interviews of the 40 subjects for this research. By adopting some time-saving measures (including training and utilizing more interviewers to allow us to more rapidly accommodate subject interviewer availability and using overnight mail for invitation letters and questionnaires), we anticipate that the conduct of these interviews can be achieved more rapidly than originally planned. Over the next several months this will mean we can also begin the coding of transcribed interviews. We have revised the Year 2 Statement of Work and are submitting for approval a new timeline for the interviewing, transcribing, coding, and analytic processes which will put us back to our original endpoints and schedule by the end of Year 2. Thus, our delays in Year 1 should not affect the ultimate outcomes and timetable for completion of this project.

Tasks:

1. **Develop interview (qualitative):** An extensive interview schedule with probe questions to guide the interviews with the 40 study subjects was finished near the end of the second quarter. This involved clarifying the many goals we have for the qualitative interview and translating these goals into questions appropriate for the age and anticipated genetic awareness of the subjects. This involves iterative attempts to word and re-word questions to avoid repetition, insure that the questions are phrased in ways which are impartial and age-appropriate and encourage open-ended, full responses. The interview outline was submitted to the Dana-Farber/Harvard Cancer Center Institutional Review Board on August 3, 2009. The interview contains sections on General Information and Current Status, Cancer Experience in the Family, Finding Out About Mother's Result, Talking with Others about Hereditary Cancer, Thinking about Counseling and Testing, Health Behaviors, Heredity in the News, Future Resources, and Response to Interview Participation.

2. **Develop questionnaire**: We developed the questionnaire which will be completed by the 40 research subjects prior to their participation in the telephone interview. This involved adapting some questions to the young adult age population being investigated in this project (for example, realizing that identification of SES was complicated by the frequent, but inconsistent financial dependence of many (but not all) in this age group, requiring changes in certain items. The questionnaire includes questions about the subject's demographics (education, employment, family income), marital status, living circumstances, parenting status, cancer family history, personal medical history, insurance status, concerns about cancer and heredity, experience with genetic counseling and/or testing. It also incorporates the 2 standard measures which are part of this study, the BSI-18 and the Erblich Breast Cancer Genetic Testing Knowledge Scale and the Impact of Event Scale, a measure commonly used in cancer genetics research. Our questionnaire has been formatted for subject ease in use and pre-tested with several non-subjects. The completed questionnaire was also submitted to the Dana-Farber/Harvard Cancer Center Institutional Review Board on August 3, 2009.

3. **Get approval from DF/HCC and USAMRMC Institutional Review Boards**: While we have approval for our study from both the Dana-Farber/Harvard Cancer Center and the USAMRMC Institutional Review Board and do have a Certificate of Confidentiality from the National Institutes of Health, we encountered delays in these aspects of the project which

have delayed our piloting our interview and questionnaire and being able to move on to conduct the study interviews.

We were delayed for more than 2 months in getting the Certificate of Confidentiality from the National Institutes of Health. While this usually has a pretty quick turnaround time, in our case this was not so, as the person assigned to review applications and grant certificates for proposals which fell under the jurisdiction of the National Human Genome Research Institute, Dr. Elizabeth Thomson, was out for surgery for several months, our application was misplaced for a while and our permission was delayed until Dr. Thomson was sufficiently recuperated to be able to read our application and grant our request for a Certificate.

After developing our questionnaires and interview schedule in the second quarter of the project as anticipated, we submitted these research materials to both IRBs. On November 27 2009, we were granted permission by the USAMRMC Institutional Review Board to begin our subject enrollment for this project. On December 3, 2009 we submitted an amendment to the DF/HCC IRB to make what we had thought would be minor changes to our protocol and patient materials to indicate that we had received our Certificate of Confidentiality, to clarify that all mothers approached would have previously given permission for research re-contact, to request permission to call mothers who had not indicated unwillingness to provide their daughter(s)' contact information 2 weeks after the sending of the letter and information form to them to insure they had received the materials and to answer any questions about the study they might have, and that we wished to add an optional space on our information form for mothers who declined to give us their daughter(s)' contact information to tell us why they were declining. We had anticipated this would be a quick process, likely an expedited process. However, this amendment was sent to the whole IRB and resulted in several written communications with the IRB. We further clarified for them that the mothers were not subjects, just informants and successfully answered all of the IRB's concerns except their request (unrelated to our amendment requests) that we add to the mother's letter a statement that the mother "has carefully considered the risks of their daughters participating in the study, including the possibility of distress and a breach of confidentiality". While we stated that we would gladly answer any questions the mother may have about this research, we are not formally asking the mother to make a decision about the risks and benefits of the research for their adult daughters. We made clear that we will fully discuss with the invited daughters, the potential participants in our study, prior to their signing (or not signing) of the consent forms, all potential risks, including those of distress and breach of confidentiality. We stated that we encourage mothers to tell their daughters that they have given us their contact information and that we make clear to the daughters that it was their mothers who gave us information to allow us to invite their participation. We had added a statement to the information form that the mothers sign stating that they understand that this information – their participation in genetic testing at a participating clinic- will be mentioned to their daughters in the explanation of why they were invited to participate. However, we did not think it advisable or accurate to ask the mothers to state they have considered the risks and benefits of the research for their adult daughters. However, the IRB did not agree with our counter-argument. While we were offered an opportunity to bring our argument to the entire IRB 3 weeks later, we instead withdrew the amendment so that we could begin our piloting

of our questionnaire and interview as soon as possible using permission granted previously by both our IRBs. This was acceptable to the DF/HCC IRB. However, this delayed until mid January our ability to send out requests to mother of eligible subjects.

4. **Consult with and review materials with consultants.** We have had several consultations with our consultants. They were all involved in reviewing the interview and questionnaire items. We also consulted with the physician consultants about a plan to access eligible subjects from their Progeny databases. We conferred on eligibility criteria and methods of using the database to access specific information about age-eligible children. Unfortunately, in December 2009, the person who has directed the DFCI Cancer Risk and Prevention Clinic registry abruptly left the clinic after 5 years and much experience with the Progeny database. Her replacement needed several months of training after being hired, but she is now up to speed and able to help us as well and has been able recently to answer questions for us from the database. We now have extensive eligibility data on nearly 200 mothers at the 3 participating hospitals who have undergone *BRCA1/2* genetic testing and have consented to further contact for research purposes. Many of these mothers have multiple age-eligible daughters. This reassures us that we will have no trouble accruing the needed 40 subjects for our research.

5. **Pilot Interviews and questionnaire**. We have now sent out 6 letters in 2 waves to mothers of age-eligible subjects seeking contact information for their daughters. We have received contact information back from 1 mother in the initial wave of 3 mothers for her 2 age-eligible daughters. It is too early to evaluate the return from the second wave. One of those daughters has been consented and she is in the process of completing her questionnaire and will be interviewed as soon as her questionnaire is returned. Her sister for whom we now have contact information will be invited to participate as a regular (not pilot) subject as soon as the piloting is complete. We will interview up to 4 additional pilot subjects (depending on the feedback we receive about the comprehensibility and clarity of the research materials from the pilot subjects). At the completion of the piloting, we will submit to both IRBs any substantive changes necessitated by pilot feedback. We will then commence writing to mothers of the potential subjects for our research and inviting subjects whose mothers provide contact information until we have our full cohort of 40 interviewed subjects.

5. **Contact Mothers for permission to contact their daughters, Accrue and Consent Patients**- we have contacted 6 mothers of potential subjects. When mothers give us permission to contact multiple daughters, we will contact one daughter as a pilot subject and will save the other names to contact once piloting is complete to interview as part of our research subject cohort. We will immediately begin accruing and consenting subjects for the main cohort when the piloting process is complete.

6. **Train Research Associate for interviewing**- We are in the process of hiring additional qualitative interviewers (1-3) for this project to allow us to shorten the time frame for conducting interviewing of research subjects. We currently have 30 interviewer resumes. We are seeking interviewers with extensive qualitative research coursework and experience in conducting qualitative interviews, anticipating that they will already be familiar with the

nuances of qualitative interviewing methods. Funds are available to do this because the project RA has worked 16 hours instead of 20 to date, anticipating that more time would be needed once interviewing began. We will begin training of these interviewers as the piloting process is on-going. (Pilot interviews will be conducted by current study staff.)

The delays recorded above have meant that we have not been able to begin to conduct the research interviews and, thus, have not been able to achieve goals 7-10 below to date. We have revised the Statement of Work to indicate our new timeline to achieve all goals previously in Years 1 and 2 by the end of Year 2. We will submit this timeline and revised SOW to Dr. Karen Wylie for her approval. We believe that we will be able to be back on the original time plan by month 24 of this project.

7. **Conduct interviews**
8. **Monitor interview quality and consistency**
9. **Transcribe interviews**
10. **Develop Coding Manual**

KEY RESEARCH ACCOMPLISHMENTS

- Development of qualitative interview for 18-24 year old daughters of women who have undergone testing for *BRCA1/2.*
- Development of demographic/family history/breast cancer genetics knowledge and distress instrument questionnaires.
- IRB approval from the DF/HCC and DOD IRBs of the methods of this research.
- Receipt of a Certificate of Confidentiality to maximize confidentiality of personal information gathered in this research effort.
- Creation of database of mothers of eligible subjects from 3 Harvard teaching hospital clinics.

REPORTABLE OUTCOMES

- As was an invited symposium speaker at the annual meeting of the American Society of Human Genetics in Honolulu in October 2009, I presented a talk entitled, "Next Generation Prevention: Educational Needs of Young At-Risk Adults" in a symposium on "Frontiers in Cancer Genetic Testing: Addressing the Needs of Children, Adolescents, and Young Adults." The talk featured the rationale and methodology of this project on 18-24 year old daughters of *BRCA1/2* mutation carriers and the DOD was credited as the sponsor of my research.

- Our interview schedule was adapted for use in other research the PI and co-Investigator Kenneth Tercyak are involved in to help formulate questions for a qualitative interview with minor children of mothers tested for *BRCA1/2.* Similarity in the format of these questions will enhance the value of both projects by allowing us to compare answers from minor and young adult children facing similar challenges as children of women tested for *BRCA1/2.*

CONCLUSIONS: As originally anticipated, we do not yet have reportable research results to report from this project.

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Erblich J, Brown K, Kim Y, et al. (2005). Development and validation of a breast cancer genetic counseling knowledge questionnaire. Patient Education and Counseling 56, 182-191

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APPENDICES – Study Questionnaires and Interview.

QUESTIONNAIRE FOR PARTICIPANTS

THANK YOU FOR PARTICIPATING IN THIS STUDY.
PLEASE FILL OUT THIS FORM AND RETURN IT IN THE ENCLOSED ENVELOPE

Study Number_____

Date you completed this form: _____

Demographics

1. Date of birth: Month: _____ Day: _____ Year: 19_____

2. Current age: _____ years old

3. Gender: ☐ Male ☐ Female

4. Race: (Check all that apply)

☐ White ☐ Black or African American ☐ Asian ☐ Hispanic/Latina

☐ American Indian/Alaska Native ☐ Native Hawaiian/ Pacific Islander

Education

5. Highest grade in school: (Check one that applies)

☐ Finished elementary or middle school

☐ High school graduate or equivalent Year graduated:_____

☐ Some college Years attended:_____

☐ College graduate -Year graduated____ Degree_____ Major:_____

☐ Post-graduate Degree: Degree _____ Field _____

☐ Other (please explain) _____

Employment

6. Occupation: _____

7. Current employment: (Check all that apply)

☐ Employed full time

☐ Employed part time

☐ Full time Student

☐ Part time Student

☐ Homemaker full time

☐ Retired

☐ Not employed- seeking work

☐ Not employed – not seeking work

Home & Family

8. Do you have sisters? (circle one) Yes No

If yes, how old are your sisters?_____

9. Do you have brothers? (circle one) Yes No

If yes, how old are your brothers?_____

10. Marital status:

- ☐ Single
- ☐ Married; Spouse's Occupation _____
- ☐ Living as Married; Partner's Occupation _____
- ☐ Separated
- ☐ Divorced
- ☐ Widow or Widower

11. If currently married: Years Since Marriage_____

12. If currently married: Spouse's **Education**

Highest grade in school: (Check one that applies)

- ☐ Finished elementary or middle school
- ☐ High school graduate or equivalent
- ☐ Some college
- ☐ College graduate
- ☐ Post-graduate Degree:
- ☐ Other (please explain) _____

13. I live most or all of the year: (Check one that applies)

- ☐ With parents, grandparents, brothers or sisters
- ☐ With wife, husband or partner
- ☐ In dorm, with or without a roommate
- ☐ With a roommate in apartment or house
- ☐ Alone

☐ Other_____

14. Household income:

☐ Under 20,000 per year

☐ Between 21,000 and 50,000 per year

☐ Between 51,000 and 100,000 per year

☐ Between $101,000-$149,000 per year

☐ Over $150,000 per year

☐ Don't know

☐ Don't want to say

15. Do you have children? ☐ Yes ☐No - If no, please skip to Question 21.

16. Number of children you have: (Please check one)

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 or more

17. Current age of daughter(s): _____

18. Current age of son(s): _____

19. Are any of these children step-children?

☐ Yes - If yes, please circle age(s) of step-child(ren) above.

☐ No

20. Are any of these children adopted?

☐ Yes - If yes, please underline age(s) of adopted child(ren) above.

☐ No

21. If it were up to you would you plan to have more children than you currently have sometime in your life? (please answer whether or not you currently have children)

☐ Yes

☐ No

Family History of Cancer

Please tell us about ANYONE in your family who has ANY type of cancer. We are interested in any cancer in a **blood relative**. A maternal relative is a blood relative on your mother's side of the family. A paternal relative is a blood relative on your father's side of the family.

22. Please tell us about the following blood relatives.

Relative	**Had Cancer?** (circle one)	**Type(s) of Cancer**	**Their Age at Diagnosis**	**Your Age when he/she Diagnosed**	**Is he/she currently living?** (circle one)	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
Mother	Yes or No				Yes or No	Yes No DK
Maternal Grandmother	Yes or No				Yes or No	Yes No DK
Maternal Grandfather	Yes or No				Yes or No	Yes No DK
Father	Yes or No				Yes or No	Yes No DK
Paternal grandmother	Yes or No				Yes or No	Yes No DK
Paternal grandfather	Yes or No				Yes or No	Yes No DK

23. Have any of your sisters had cancer? (circle one) Yes No (if no, or no sisters, please skip to Question 24).

For each blood-related **sister** who had cancer, list the type(s) of cancer, her age when the cancer was found, your age at that time and answer the other two questions.

Sister	**Type(s) of Cancer**	**Her Age at Diagnosis**	**Your Age when her cancer was found**	**Is she currently living?** (circle one)	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
1				Yes or No	Yes No DK
2				Yes or No	Yes No DK
3				Yes or No	Yes No DK
4				Yes or No	Yes No DK

24. Have any of your brothers ever had cancer? (cir cle one) Yes No (if no, or no brothers, skip to Question 25).

For each blood-related **brother** who had cancer, list the type(s) of cancer, his age when the cancer was found, your age at that time and answer the other 2 questions.

Brother	**Type(s) of Cancer**	**His Age at Diagnosis**	**Your Age when his cancer was found**	**Is he/she currently living? (Circle one) (DK=Don't know**	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
1				Yes or No	Yes No DK
2				Yes or No	Yes No DK
3				Yes or No	Yes No DK
4				Yes or No	Yes No DK

25. Do you have any other blood relatives who have had cancer? This could include aunts (sisters of your mother or father) or uncles (brother of your mother or father) or cousins.

☐Yes ☐ No- Skip to Question 26.

For each of your other blood relatives, who had cancer, list how he or she is related to you (your maternal aunt, paternal uncle, maternal first cousin, etc.), the type(s) of cancer, how old he/she was when the cancer was found and your age when their cancer was found.

Relation to you	**Type(s) of Cancer**	**His/Her Age at Diagnosis**	**Your Age when cancer was found**	**Is he/she currently living? (Circle one) (DK=Don't know**	**If person is not living, did they die of cancer? (Circle one) (DK=Don't know)**
1.				Yes No DK	Yes No DK
2.				Yes No DK	Yes No DK
3.				Yes No DK	Yes No DK
4.				Yes No DK	Yes No DK

Insurance

26. I have: (Check one that applies)

☐ Health insurance through my work

☐ Health insurance through my spouse's work

☐ Health insurance through my parents

☐ Health insurance from another source:

_____

☐ No health insurance

27. I have:

Disability insurance ☐ Yes ☐ No

Life insurance ☐ Yes ☐ No

28. Do you think you have ever been denied or had difficulty getting any type of insurance due your family history or a known predisposition to cancer?

☐ Yes - If yes, please explain below. ☐ No

_____

_____

Personal Medical History

29. Do you have any significant health problems?

☐Yes- If yes, please list below ☐ No

_____

_____

Concerns about Cancer & Heredity

30. Do you think the cancer in your family was due to an inherited predisposition to cancer in your family?

☐ Definitely not ☐ Probably not ☐ Don't know ☐Probably ☐Definitely was

31. How much do you worry about cancer risk being inherited in your family?

☐ Not at all ☐ A little ☐ Quite a bit ☐ A great deal ☐ To an extreme

32. How much do you worry about getting cancer in the future?

☐ Not at all ☐ A little ☐ Quite a bit ☐ A great deal ☐ To an extreme

33. How much you would say you worry about whether your child/children (present or future children) will develop cancer in the future?

☐ Not at all ☐ A little ☐ Quite a bit ☐ A great deal ☐ To an extreme

Discussion with Professionals

34. Have you ever spoken to any of these professionals about cancer and heredity? (Check all that apply)

☐Internist/Primary Care Doctor ☐Gynecologist ☐ Oncologist ☐Other doctor_____
☐ Your child's pediatrician ☐ Genetic counselor/Geneticist
☐ Nurse ☐ Social Worker ☐ Psychotherapist
☐Others (who?) _____
☐ NONE OF THE ABOVE

35. Have you ever:

Had Cancer Genetic Counseling	☐Yes	☐ No	☐Don't know
Had Genetic Testing for cancer gene	☐Yes	☐ No	☐Don't know
Gotten cancer genetic test result	☐Yes	☐ No	☐Don't know
If tested, test result was	☐Positive	☐Negative	☐Indeterminate

BREAST CANCER GENETICS QUESTIONNAIRE

Please answer all of the questions below. Feel free to say you don't know. Genetic medicine is a new field and many professionals are taking courses to learn about the genetic advances in recent years. So, please do not feel badly if you do not know all the answers. But please do try to give one answer for each item.

CIRCLE THE ANSWER YOU BELIEVE IS CORRECT:

	True	False	Don't Know
1.50% of inherited genetic information (about breast cancer risk) is passed down from a person's mother.	True	False	Don't Know
2. 25% of inherited genetic information (about breast cancer risk) is passed down from a person's father.	True	False	Don't Know
3. There is more than one gene that can increase the risk of breast cancer.	True	False	Don't Know
4. A woman who has a sister with a breast cancer gene mutation has a 1 in 4 chance of having a gene mutation herself.	True	False	Don't Know
5. A father can pass down a breast cancer gene mutation to his daughters.	True	False	Don't Know
6. One in 10 women has a breast cancer gene mutation.	True	False	Don't Know
7. All women who have a breast cancer gene mutation will get cancer.	True	False	Don't Know

If the currently available genetic tests were to indicate that a woman has a breast cancer gene mutation, she is at increased risk for:

8. Breast cancer	True	False	Don't Know
9. Ovarian cancer	True	False	Don't Know
10. Lung cancer	True	False	Don't Know
11. Bladder cancer	True	False	Don't Know

If a woman who already had breast cancer was found to have a breast cancer gene mutation, she is at increased risk for developing:

12. Another breast cancer	True	False	Don't Know
13. Ovarian cancer	True	False	Don't Know
14. Lung cancer	True	False	Don't Know
15. Bladder cancer	True	False	Don't Know

16. Women who test positive for breast cancer mutations are generally more likely to develop breast cancer at a young age	True	False	Don't Know
17. A man who carries a breast cancer gene mutation has an increased risk of developing breast cancer himself.	True	False	Don't Know
18. If a woman tests positive for a breast cancer gene mutation, her male relatives' risk for developing prostate cancer are lowered.	True	False	Don't Know
19. A woman may be at greater risk for developing ovarian cancer if she has several close relatives with ovarian cancer.	True	False	Don't Know
20. A woman may be at greater risk for developing ovarian cancer if she has several close relatives with breast cancer.	True	False	Don't Know
21. A woman who has her healthy ovaries removed will definitely not get ovarian cancer.	True	False	Don't Know
22. A woman who has her breasts removed will definitely not get breast cancer.	True	False	Don't Know
23. Screening for ovarian cancer often does not detect a tumor until it is more advanced.	True	False	Don't Know

Directions:
Please check one answer for each question #24-27.

24. How many copies of a non-working breast cancer gene must one inherit to be at inherited risk for breast cancer?

☐ a. 0 c.3 ☐

☐ b. 1 d. ☐ Don't know

25. What is the approximate risk that the average women in the United States will develop breast cancer in her lifetime:

☐ a. 12% ☐ d. 72%

☐ b. 24% ☐ e. Don't know

☐ c. 58%

26. If a genetic test were to indicate that a woman inherited a breast cancer gene mutation, then how likely is she to develop breast cancer in her lifetime?

☐ a. Up to 15% chance ☐ d. up to 50% chance

☐ b. Up to 25% chance ☐ e. up to 85% chance

☐ c. Up to 40% chance ☐ f. Don't know

27. Select the procedure that is NOT appropriate for the detection of ovarian cancer:

☐ a. ultrasound d. ☐ pelvic examination

☐ b. pap smear ☐ e. Don't know

☐ c. CA-125 blood test

Directions:
Indicate how frequently each of these comments was true for you during the past seven days in relation to **inherited predisposition to breast/ovarian cancer.** Please **circle the word that best fits your experience over the past 7 days.**

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.	Not at all	Rarely	Sometimes	Often
2. I avoided letting myself get upset when I thought about it or was reminded of it.	Not at all	Rarely	Sometimes	Often
3. I tried to remove it from memory.	Not at all	Rarely	Sometimes	Often
4. I had trouble falling asleep or staying asleep because of thoughts about it that came into my mind.	Not at all	Rarely	Sometimes	Often
5. I had waves of strong feeling about it.	Not at all	Rarely	Sometimes	Often
6. I had dreams about it.	Not at all	Rarely	Sometimes	Often
7. I stayed away from reminders of it.	Not at all	Rarely	Sometimes	Often
8. I felt as if it hadn't happened or wasn't real.	Not at all	Rarely	Sometimes	Often
9. I tried not to talk about it.	Not at all	Rarely	Sometimes	Often
10. Pictures about it popped into my head.	Not at all	Rarely	Sometimes	Often
11. Other things kept making me think about it.	Not at all	Rarely	Sometimes	Often
12. I tried not to think about it.	Not at all	Rarely	Sometimes	Often
13. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	Not at all	Rarely	Sometimes	Often
14. Any reminder brought back feelings about it.	Not at all	Rarely	Sometimes	Often
15. My feelings about it were kind of numb.	Not at all	Rarely	Sometimes	Often

THIS PAGE WILL BE SEPARATED FROM THE QUESTIONNAIRE WHEN RECEIVED

Could you please tell us when it would be best for us to try to reach you to schedule our phone interview for this project:

Best times:_____

Best days:_____

Phone numbers: Please give us your phone numbers and tell us if it ok to call that number to reach you

Day:_____ ☐ ok to call

Evening or weekends:_____ ☐ ok to call

Cell:_____ ☐ ok to call

THANK YOU.

PLEASE RETURN TO US <u>WITH ONE SIGNED COPY OF THE CONSENT FORM</u> IN

THE STAMPED ENVELOPE PROVIDED.

Return to: **Dr. Andrea Patenaude**
Dana-Farber Cancer Institute
44 Binney Street
Boston, MA 02115

INTERVIEW SCHEDULE:

PARTICIPANT NUMBER: _____ INTERVIEWER:_____

START TIME: _____ END TIME: _____

INTERVIEW LENGTH (MINUTES): _____

FIRST, THANK YOU VERY MUCH FOR YOUR WILLINGNESS TO PARTICIPATE IN THIS INTERVIEW.

THE GOAL OF THIS PROJECT IS TO LEARN AS MUCH AS WE CAN ABOUT HOW YOUNG WOMEN WHOSE FAMILIES HAVE BEEN AFFECTED BY CANCER OR THE RISK OF CANCER THINK ABOUT RISKS FOR THEMSELVES AND OTHERS AND HOW THEY THINK ABOUT THEIR OWN HEALTH. WE ARE HOPING THAT YOU CAN HELP US TO PLAN HOW TO TALK TO OTHER YOUNG PEOPLE YOUR AGE ABOUT THESE THINGS.

WE ARE VERY INTERESTED IN YOUR THOUGHTS AND OPINIONS, SO PLEASE TAKE AS LONG AS YOU LIKE TO ANSWER OUR QUESTIONS.

I WOULD LIKE TO SAY AGAIN THAT YOU ARE FREE NOT TO ANSWER ANY QUESTION YOU DON'T WANT TO ANSWER AND YOU CAN ALSO STOP THE INTERVIEW AT ANY TIME. ALSO, FEEL FREE TO SAY I DON'T KNOW AT ANY POINT. WE DO NOT EXPECT THAT YOU WILL KNOW THE ANSWERS TO ALL THE QUESTIONS WE ASK.

BEFORE WE BEGIN, ARE THERE ANY QUESTIONS YOU WOULD LIKE TO ASK ME?

GENERAL INFORMATION- CURRENT STATUS

1. First, Can you please start by telling me a bit about yourself, about your life currently – where are you in school or work, what do you think about for your future, what's most important to you now?

2. How do you think about your own health now?

3. Do you think at all about insurance – health, life, disability? If so, what do you think?, do?

4. Do you do anything in particular to try to stay healthy? If yes, What do you do?

CANCER

1. Would you say that cancer runs in your family?

2. How you would say cancer or the risk of getting cancer has affected your family?

3. How much do you worry about getting cancer yourself? What triggers your worries? What is your specific worry, if any? Do you tell anyone about that worry?

4. How much do you worry about other people in your family getting cancer (or getting cancer again?) Who do you worry about?

5. Who in your family has had genetic testing for cancer genes?

6. How did you find out that your mother (or other relatives) had been tested?

Relationship	gene tested	when done	result	S's reaction

FINDING OUT

1. How did you find out that your mother (or other relatives) had been tested?
   Probes: If not clear: Did you go with your mother when she was tested? When she got her result? Whenever daughter was informed: What exactly were you told? How old were you? Do you know what gene she was tested for? And what was found? How long after your mother knew the result? Who was present when you were told? Who spoke? Do you remember what went through your head as you were being informed? How did you react immediately? Later? When has it come up subsequently? How often? What brings it up?

2. Did the person informing you have any particular message they were trying to get across about the meaning of this information either for themselves or for you? If yes, what message? How did you receive the message?

3. How do you now think about the meaning or importance of this information to you?
   Probe: Did this information change how you think about cancer and your family? (Clarify if not clear, if daughter herself has been tested and, if so, how that changed meaning or importance of the genetic information for her)

4. What type or types of cancer does this information relate to for you or for other members of your family?

5. Did having this information (either mother's result or, if tested herself, mother's and her result), change any of your thinking about your future, either what you might want to do or the timing of what you plan to do?

TALKING WITH OTHERS

1. Were you given any guidelines about people to talk to or not talk to about it? Whom have you talked with about this information? How have these discussions gone?
   Probes: a. Mother b. Father c. Sisters d. Brothers e. Other relatives
   f. Friends g. Boy Friend or Girl Friend

2. Have you talked to any medical professional about inherited cancer risk?
   If no: has it just not come up or did you choose not to speak about it?
   If yes: who did you talk to , how did it come up , about what, how did you feel about those conversations?
3. Have you spoken to anyone else who is in a position similar to yours, i.e. having a tested relative? How was that for you?

4. Was there anyone you wanted to speak to about this who you haven't been able to talk to?
   If yes: whom? why wasn't it possible?

5. Have there been times when you wanted to hear less about genetics or genetic testing or related matters, when you wished people didn't talk about it to you so much?
   If yes: could you tell us about those times?

6. Are there things you wish you knew or understood better about this area? Things you wish you didn't know or feel you would have been better off not knowing?

7. Based on your own experience, what do you think is the ideal age or time for parents to talk to their children about their own hereditary cancer risk or test results?

THINKING ABOUT COUNSELING AND TESTING

1. How old were you when you learned that there was testing YOU could have at some point in your life which could tell you about your own hereditary cancer risks? How did you feel about testing then? How now? How much do you think about testing?

2. Have your parents given you advice about getting tested, either whether to have it or when to have it? Has anyone else talked to you about genetic testing for yourself?

3. Have you ever spoken to a genetic counselor?
   If yes: how did that come about? Who went? How was it for you? What did you learn?
   If no,: did you even want to? Would you know how to find a genetic counselor?

4. Have you ever seen any ads on TV or in magazines about testing for hereditary cancer genes?
   If yes: what effect, if any, did the ads have on you?

5. If clear S has been tested, skip to Q. 6. What do you think now about getting tested? If not tested, do you have a clear idea of what you want to do? If so, what? What are the pros and cons? Thoughts about testing later on in life? Never? Need more info to decide? Where would you get that info? (Skip to Question 8).

6. If she decides she wants to be tested, what do you think is the best age for a girl like you to get genetic testing?

7. (If already tested) How did your testing come about? How did it feel to wait for results? Have you gotten results? What was your reaction to results?
   If got results: how did you feel about your result?
   If not gotten results: do you have a plan for getting them or just know not now?

8. (If already tested) Whom have you told about your test result? Family? Friends? Doctors?

9. Is there an age or a time in one's life when it would be ideal to get testing?
   What do you think should be the youngest age at which people with hereditary cancer risk in their family should be able to be tested to see if they carry that increased risk (minimal age)?

10. Do you think there should be genetic counseling for kids before the age when they can usually be tested to answer questions about genetic risk?
    If yes: how should it work?

HEALTH BEHAVIORS

1. When do you go to a doctor?
   Probes: How often, what type, feel like your doctor really knows you? Do your doctors know about hereditary risk in your family? your result (if appropriate)?

2. Has anyone talked to you about things that you can do to try to prevent cancer either now or in the future?
   If yes: Who? What? When? How did you feel when these things were brought to your attention? (Probe: Hopeful, Avoidant or Other feelings) How often do you think about these things? How do you feel when you think about those things now?
   If no: skip to Q. 3.

3. Do you do anything to try to prevent cancer that is related to knowledge of hereditary cancer risk?

4. At what age do you think you will start having mammograms? How often would you plan to have them then? How would you arrange to have a mammogram? How do you think they will get paid for?

5. Is there anything else you know of that a woman who might be at hereditary risk for cancer might do to reduce her risk of cancer?

6. Are there/Were there things that your mother or other relatives have done/did to try to prevent cancer? Do you know other people who are doing special screening or other things because of having hereditary cancer risk? How did you feel about her doing those things? Does her experience influence your thoughts about what you might do?

7. Have you ever heard of any of the following? If yes, what have you heard about them?
   Breast MRIs
   Clinical breast exams
   Breast self-examination
   Prophylactic or risk-reducing mastectomy
   Prophylactic or risk-reducing oophorectomy
   CA-125 test
   Transvaginal ultrasound

HEREDITY IN THE NEWS

1. Where do you get most of your information about hereditary cancer or genetic testing?

2. How often do you come upon an article or program about cancer and genetics? Do you typically read it or listen or not? How do you find the level of the information?

FUTURE RESOURCES

1. How much do young people who are from families with increased hereditary cancer risks want to know about the risk and their options? When and how should it be discussed?

2. Would it be helpful if there were an information source geared specifically to young people who might have such hereditary risk?
   If not: why not?
   If so: what format would be best (written brochure, video, Internet website, other)? What should it include? Not include? Who should deliver the message? Can you imagine a situation where you might use this information source?

RESPONSE TO PARTICIPATION Subject Feedback Section

Thank you for taking the time to participate in this interview. Now I would just like to ask you a few more questions about how it was for you to participate in this interview.

1. . How have you felt answering these questions today?

2. Did you feel distressed in any way by any aspect of participating in this study?
   If yes- Can you tell me a bit about what caused you distress? How distressing was it?

3. Did you find participating in this interview helpful in any way?
   If yes- In what way(s)

4. Were there any questions you didn't like or that we could have asked in a better way?
   If yes- Which questions?

5. Are there important questions for cancer survivors related to cancer and heredity which we have left out?

6. Is there anything that you would like to know more about that we talked about or touched on today?

Thank you. (Turn off tape recorder).

Confirm address as to where the honoraria should be sent.

END TIME: _____